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Applying expert knowledge to ensure QA and QC compliance

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QA and QC Compliance Strategies for Biopharmaceuticals

Establishing, maintaining and remediating
appropriate compliance strategies

Course Dates:

2-3 February 2011, MWB, Victoria, London, UK

13-14 July 2011, MWB Victoria, London, UK

Obtain a broad, clear view and develop a greater understanding of:

- The role of quality in the production and testing of biopharmaceutical products
- The relationship of recent and emerging ICH guidance documents on quality systems to current requirements for cGMP
- The nature of compliance activities that verify the suitability of the quality system
- Recent trends in inspectional observations and warning letters for compliance failures in production and testing quality systems



For more information go to www.pti-europe.co.uk/QAQCbio

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QA and QC Compliance Strategies for Bio

Course Agenda Registration will be at 9.00am, the course will start at 9.15am and will finish by 5.00pm

Course Overview

Biotechnology products are intended to be produced under cGMP conditions with the support of a reliable and credible quality system. In order to generate - then verify - sound scientific and operational practices, the quality system should comprise prospective elements of Quality by Design as well as retrospective elements of review and inspection. This course will present critical factors to consider in establishing, maintaining and/or remediating appropriate compliance strategies in the production and testing of biopharmaceutical products. Current ICH documents defining requirements for quality assurance throughout the product lifecycle will be reviewed. Practical examples will be presented based on the extensive technical, regulatory and quality expertise of the course instructors from their combined experiences in regulatory agencies as well as both pharma and contract organisations. Specific QA/QC considerations for biologically-derived products will be discussed.

This systematic, comprehensive class will include the following issues:

DAY 1

- An overview of typical production and testing operations for biotechnology-derived products
- Key elements of biological manufacturing that merit additional QA attention
- Unique aspects of biopharmaceutical products requiring enhanced QC to assure product safety
- Recommended QA approaches to the major biopharm systems:
 - Production
 - Facilities and equipment
 - Laboratory controls
 - Materials
 - Packaging and labelling

DAY 2

- Elements of a sound quality management system
- Practical aspects of linking quality management to operations
- Lifecycle considerations in quality management
- QA/QC considerations in small versus large organizations
- Hot topics in inspections of biotechnology manufacturing facilities
- Hot topics in inspections of biotechnology testing laboratories
- How ICH quality guidance documents support the strategic implementation and routine management of QA/QC functions

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Course Curriculum:

To find out more about related PTI courses, please contact our account management team on +44 (0) 20 7017 7267/7159/7164

Course Objectives:

- Review of current regulatory expectations for product lifecycle quality management systems.
- Outline of major elements of sound QA/QC practices for biotechnology product manufacturing and testing operations.
- Overview of recent hot button QA/QC deficiencies found in regulatory inspections

Performance & Knowledge Objectives of this Course:

By attending this course, participants should obtain a clear, concise view of the types of QA and QC activities necessary for biologically-based products from preclinical/clinical development to commercialisation. They should be able to identify the major elements of a quality management system applicable to biotechnology production processes and testing laboratories. Practical aspects of quality audits and inspections will be presented to illustrate best practices in biotechnology QA roles and responsibilities. Finally, attendees will be shown recent warning letters from regulatory inspections to provide a real-world perspective of common deficiencies to be avoided in pharmaceutical production and testing operations.

Who are your Trainers?

Dr Ruth Wolff, Senior CMC Consultant, Biologics Consulting Group, USA

Over the course of her academic and professional career, Dr Wolff progressed from basic research through increasingly applied research in somatic cell/medical genetics and identification of epitopes for vaccine development, to cell line safety testing for biopharmaceuticals in a natural evolution toward regulatory review. While at the FDA, she participated directly in the regulatory activities in application review, policy development, and international regulatory coordination. During this time, as researcher, reviewer and manager, she acquired experience with a wide range of disciplines and technologies, sponsors and products, submissions and processes, with the goal of bringing safe and effective products to the public in a timely manner. In her current role and CMC consultant, she is responsible for the scientific and regulatory review and analysis of a wide range of therapeutic products at all stages of product development, from pre-IND development through post-marketing. She provides regulatory, scientific and manufacturing analysis and support, develops product-and facility-related regulatory documents for submission, reviews SOPs and validation packages and performs facilities audits for a wide array of biotechnology products world-wide.

Dr Nadine M. Ritter, Senior CMC Consultant, Biologics Consulting Group, USA

Nadine Ritter has been a protein scientist for over 25 yrs, first as funded academic research in bone biology, followed by a move to the biotechnology industry in 1998. There she acquired direct experiences as a senior scientist in large pharma organisation, conducting analytical studies to support product quality testing and regulatory filings. She was then recruited to become director of the analytical services division of a major biotech contract lab performing R&D, GLP and GMP studies and tests. During her tenure, her lab generated product characterisation, comparability, release and stability data to support the development and commercialisation of a wide array of biotechnology products. Currently, she is a CMC technical, regulatory and quality consultant in the biopharmaceutical industry, and is an instructor in post-graduate academic programmes for biotechnology education. Dr Ritter is on the board of several biotechnology professional organisations, academic institutions and journals. She has given invited presentations around the world, and has written numerous articles and book chapters as a subject matter expert. She is a recognised leader in the technical, quality and regulatory elements of analytics for a variety of biotechnology, biological and biosimilar products. Nadine has been a popular and highly-rated PTI trainer since 2001.

Tailored Training Solutions

All PTI's training courses can be customised to meet exact requirements and delivered by our experienced trainers on-site.

- Save valuable time and expenditure
- Address your teams' specific needs with a tailored training approach
- Find solutions to real problems by incorporating your own case studies and examples
- Increase communication and performance by training your department as a team

For more details or initial consultation, please contact the PTI Tailored Training Team, on +44 (0) 20 7017 7266 or email tailoredtraining@pti-europe.co.uk



QA and QC Compliance Strategies for Biopharmaceuticals

2-3 February 2011, MWB Victoria, 10 Greycoat Place, Westminster, London, SW1P 1SB
13-14 July 2011, MWB Victoria, 10 Greycoat Place, Westminster, London, SW1P 1SB

Course code: CSN401
Course code: CSN402

FIVE EASY WAYS TO REGISTER

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Email: registration@pti-europe.co.uk



Fax: Complete and send this registration form to: +44 (0) 20 7017 7823



Web: www.pti-europe.co.uk/QACCbio



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HOW MUCH?

Course fee includes: workbook, lunch, refreshments, post-event follow up call

Ticket	Date	Code	Full Price	VAT	TOTAL PRICE
<input type="checkbox"/>	2-3 February 2011	GSN401	£1445.00	£216.75	£1661.75
<input type="checkbox"/>	13-14 July 2011	CSN402	£1445.00	£216.75	£1661.75

The VAT rate is subject to change and may differ from the advertised rate. The amount you are charged will be determined when your invoice is raised.

Please send me information on onsite training

If booking 4 weeks or more in advance, tick here to receive £100 off the Full Price

Yes! I would like to receive information about future events and services via fax SMS/MMS

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What Happens if I Have to Cancel? Confirm your CANCELLATION in writing 2 weeks before the date of the course (9th January 2011, CSN401/2 and 6 June 2011, CSN402) and receive a refund less a 30% + VAT service charge. Should you cancel between this date and 1 week before the date of the course (28th January 2011, CSN401/2 and 30 June 2011, CSN402) then you will receive a refund less a 100% + VAT service charge. Regrettably, no refunds can be made for cancellations received less than one week prior to the conference. Within 10 working days prior to the start date of the course the Customer may reschedule a booking to another date at a 30% rescheduling fee or within 46 hrs of a 100% rescheduling fee by advising Pharmaceutical Training International UK or such rescheduling in writing. For full terms and conditions visit www.pti-europe.co.uk/terms

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Additional Requirements: Please notify IIR at least one month before the course date if you have any additional requirements e.g. wheelchair access, large print etc.